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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,276	04/24/2001	John R. Hadcock	PC10834ATMC	6011

7590 08/30/2002

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EXAMINER
NICHOLS, CHRISTOPHER J

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 08/30/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/841,276	HADCOCK, JOHN R.	
	Examiner	Art Unit	
	Christopher Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-16* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 (in part), 2 (in part), 5 (in part), 7, and 8 drawn to a method of administering neurotensin-1 agonist to a patient who is, or is at risk of becoming, obese, classification dependent on agent structure.

II. Claims 1, 2, and 6 (each in part) drawn to a method of administering neurotensin-1 antagonist to a patient who is, or is at risk of becoming, obese, classification dependent on agent structure.

III. Claims 1, 2, and 5 (each in part) drawn to a method of administering neurotensin-2 agonist to a patient who is, or is at risk of becoming, obese, classification dependent on agent structure.

IV. Claims 1, 2, and 6 (each in part) drawn to a method of administering neurotensin-2 antagonist to a patient who is, or is at risk of becoming, obese, classification dependent on agent structure.

V. Claims 1, 4, and 5 (each in part) drawn to a method of administering neurotensin-3 agonist to a patient who is, or is at risk of becoming, obese, classification dependent on agent structure.

VI. Claims 1, 4, and 6 (each in part) drawn to a method of administering neurotensin-3 antagonist to a patient who is, or is at risk of becoming, obese, classification dependent on agent structure.

VII. Claims 9, 10, 11, 12, 13, and 14 (each in part) drawn to a pharmaceutical composition or kit comprising neurotensin-1 agonist and a second compound, classification dependent on agent structure.

VIII. Claims 9, 11, 12, and 14 (each in part) drawn to a pharmaceutical composition or kit comprising a neurotensin receptor ligand other than a neurotensin-1 agonist and a second compound, classification dependent on agent structure.

IX. Claims 15 and 16 (each in part) drawn to methods treating various disease comprising administering neurotensin-1 receptor ligand, classification dependent on agent structure.

X. Claim 15 (in part) drawn to methods treating various disease comprising administering neurotensin receptor ligand other than neurotensin-1, classification dependent on agent structure.

2. Claim 11 has been interpreted as being directed to a pharmaceutical composition rather than a method. This interpretation is based on Claim 11's dependence from and further limiting of Claim 9.

3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to <u>different</u> methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I, II, III, IV, V, and VI are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires search and consideration of neurotensin-1 receptor agonists, which is not required by

any of the other groups. Invention II requires search and consideration of neurotensin-1 receptor antagonists, which is not required by any of the other groups. Invention III requires search and consideration of neurotensin-2 receptor agonists, which is not required by any of the other groups. Invention IV requires search and consideration of neurotensin-2 receptor antagonists, which is not required by any of the other groups. Invention V requires search and consideration of neurotensin-3 receptor agonists, which is not required by any of the other groups. Invention VI requires search and consideration of neurotensin-3 receptor antagonists, which is not required by any of the other groups. Therefore, a search and examination of all of the methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions IX and X are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention IX requires search and consideration of a neurotensin-1 agonist which is not required of Invention X. Therefore, a search and examination of all of the methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

5. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the

following reasons. Inventions VII and VIII are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Invention VII recites the requirement of a neurotensin-1 agonist which is not required for the composition of Invention VIII.

6. Inventions VII and each of II, III, IV, V, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VII and each of II, III, IV, V, and VI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions II, III, IV, V, and VI do not recite the use or production of the pharmaceutical composition or kits of Invention VII.

7. Inventions VII and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compounds of Invention VII can be used in materially different methods other than the methods of Invention I, such as in diagnostic methods (e.g., in screening) or biochemical methods (e.g. isolating receptors).

8. Inventions VIII and each of I, II, III, IV, V, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VIII and each of I, II, III, IV,

V, and VI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, II, III, IV, V, and VI do not recite the use or production of the pharmaceutical composition or kits of Invention VIII.

9. Inventions IX and each of I, II, III, IV, V, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions IX and each of I, II, III, IV, V, and VI are unrelated methods, wherein each is not required, one for another. For example, the methods of Inventions I, II, III, IV, V, and VI are intended for a different patient population than Invention IX.

10. Inventions X and each of I, II, III, IV, V, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions IX and each of I, II, III, IV, V, and VI are unrelated methods, wherein each is not required, one for another. For example, the methods of Inventions I, II, III, IV, V, and VI are intended for a different patient population than Invention X.

11. Inventions IX and each of VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions IX and each of VII and VI are unrelated method and products, wherein each is not required, one for another. For example, the claimed

methods of Inventions IX do not recite the use or production of the pharmaceutical composition or kits of Invention VII and VIII.

12. Inventions X and each of VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions X and each of VII and VI are unrelated method and products, wherein each is not required, one for another. For example, the claimed methods of Inventions X do not recite the use or production of the pharmaceutical composition or kits of Invention VII and VIII.

13. This application contains claims directed to the following patentably distinct species of the claimed invention:

a. Obesity

b. Diabetes impaired

c. Insulin resistance

d. Glucose tolerance

e. Sexual dysfunction

f. Atherosclerosis

g. Hypercholesterolemia

h. Hypertrigylceridemia

14. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 9 is generic.

15. If applicant selects Inventions VII or VIII one species from the disease targeted by a second compound group must be chosen to be fully responsive.

16. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

17. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

18. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

19. This application contains claims directed to the following patentably distinct species of the claimed invention:

i. A β_3-adrenergic receptor agonist

j. A cholecystokinin-A agonist

k. A monoamine reuptake inhibitor

l. A sympathomimetic agent

m. A sertotoninergic agent

n. A dopamine agonist

o. A melanocyte-stimulating hormone receptor agonist or mimetic or analog

p. A cannabinoid receptor antagonist

q. A melanin concentrating hormone antagonist

r. Leptin or analog or a leptin receptor agonist

s. A galanin antagonist

t. A bombesin agonist

u. A neuropeptide-Y antagonist

v. A thyromimetic agent

w. Dehydroepiandrosterone or an analog thereof

x. A glucocorticoid receptor agonist or antagonist

y. An orexin receptor antagonist

z. A urocortin binding protein antagonist

aa. A glucagons-like peptide-1 receptor agonist

bb. A ciliary neurotrophic factor

20. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 11 is generic.

21. If applicant selects Inventions VII or VIII one species from the disease targeted by a second compound group must be chosen to be fully responsive.

22. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

23. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

24. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

25. This application contains claims directed to the following patentably distinct species of the claimed invention:

cc. Obesity

dd. Diabetes impaired

ee. Insulin resistance

ff. Glucose tolerance

gg. Sexual dysfunction

hh. Atherosclerosis

ii. Hypercholesterolemia

jj. Hypertrigylceridemia

26. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 12 is generic.

27. If applicant selects any one of Inventions VII or VIII one species from the disease targeted by a second compound group must be chosen to be fully responsive.

28. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

29. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

30. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

31. This application contains claims directed to the following patentably distinct species of the claimed invention:

kk. A β_3-adrenergic receptor agonist

ll. A cholecystokinin-A agonist

mm. A monoamine reuptake inhibitor

nn. A sympathomimetic agent

oo. A sertotoninergic agent

pp. A dopamine agonist

qq. A melanocyte-stimulating hormone receptor agonist or mimetic or analog

rr. A cannabinoid receptor antagonist

ss. A melanin concentrating hormone antagonist

tt. Leptin or analog or a leptin receptor agonist

uu. A galanin antagonist

vv. A bombesin agonist

ww. A neuropeptide-Y antagonist

xx. A thyromimetic agent

yy. Dehydroepiandrosterone or an analog thereof

zz. A glucocorticoid receptor agonist or antagonist

aaa. An orexin receptor antagonist

bbb. A urocortin binding protein antagonist

ccc. A glucagons-like peptide-1 receptor agonist

ddd. A ciliary neurotrophic factor

32. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 14 is generic.

33. If applicant selects any one of Inventions VII or VIII one species from the disease targeted by a second compound group must be chosen to be fully responsive.

34. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

35. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

36. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

37. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search

requirements, and/or different classification, restriction for examination purposes as indicated is proper.

38. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

39. This application contains claims directed to the following patentably distinct species of the claimed invention:

eee. Diabetes

fff. Sexual dysfunction

ggg. Atherosclerosis

hhh. Insulin resistance

iii. Impaired glucose tolerance

jjj. Hypercholesterolemia

kkk. Hypertriglyceridemia

40. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 15 is generic.

41. If applicant selects any one of Inventions IX or X one species from the disease targeted by a second compound group must be chosen to be fully responsive.

42. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

43. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

44. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

45. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

46. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

47. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Nichols, Ph.D. whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

48. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone number for the customer service center is 703-872-9305.

49. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
August 28, 2002

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER